

**COPY**

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

SUSAN CHRISTENSEN,

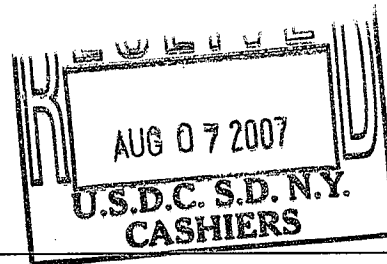
Plaintiff,

vs.

MERCK & CO., INC. and  
NOVARTIS PHARMACEUTICAL  
CORPORATION,

Defendant.

**07 CV 7053**  
Civil Action No.: \_\_\_\_\_



COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Susan Christensen ("Plaintiff"), by her attorneys, for her Complaint against defendants Merck & Co., Inc. ("Merck") and Novartis Pharmaceutical Corporation ("Novartis") (also, collectively, "defendants"), alleges:

**I. JURISDICTION AND VENUE**

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendants. Plaintiff is a resident of the State of Utah. Defendant Merck is incorporated and has its primary business in the State of New Jersey. Defendant Novartis is incorporated and has its primary business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.

2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

3. This is a civil action for damages suffered by Plaintiff as a result of her being prescribed and ingesting Merck's drug Fosamax and Novartis' drugs Aredia and Zometa.

## **II. PARTIES**

4. Plaintiff Susan Christensen was born January 14, 1949. At all relevant times Plaintiff was a resident of the State of Utah.

5. At all times herein mentioned, Defendant Merck was and is a New Jersey corporation, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

6. At all times herein mentioned, Defendant Novartis was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

7. At all times herein mentioned, Defendants did business in the State of Utah.

## **III. SUMMARY OF THE CASE**

8. Defendant Merck, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

9. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff Susan Christensen, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.

10. Defendant Merck concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff Susan Christensen, other consumers, and the medical community.

11. Defendant Merck failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

12. As a result of Defendant Merck's actions and inaction, Plaintiff Susan Christensen was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages.

#### **IV. FACTUAL BACKGROUND**

13. At all relevant times, Defendant Merck was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

14. At all relevant times, Defendant Novartis was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing and selling AREDIA and ZOMETA.

15. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.

16. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

17. Novartis manufactured ZOMETA as the successor-drug to AREDIA. Taking AREDIA and then ZOMETA increases the risk of osteonecrosis of the jaw, including the maxilla (bone). Taking AREDIA and then ZOMETA causes osteonecrosis of the bone.

18. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (Actonel); and alendronate (Fosamax). The non-nitrogenous bisphosphonates

include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

19. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

20. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

21. Merck knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

22. In 2002 or before, Merck knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

23. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

24. Shortly after Merck began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

25. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

26. Since FOSAMAX was released, the FDA has received a number of reports osteonecrosis of the jaw among users of FOSAMAX.

27. On August 25, 2004, the FDA posted its ODS (Office of Drug Safety) Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

28. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect, which specifically extended to the oral bisphosphonate, FOSAMAX.

29. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

30. Novartis made labeling changes in September and October of 2003, but these changes were inadequate to warn consumers and health care providers, and remain so to this date.

31. In 2002 or before, Merck knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

32. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa, also a bisphosphonate. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

33. In September 2004 and May 2005, another manufacturer sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of its bisphosphonates, Aredia and Zometa.

34. Rather than warn patients, and despite knowledge known by Defendant Merck about increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.

35. FOSAMAX is one of Merck's top selling drugs. Averaging more than \$3 billion a year in sales.

36. Consumers, including Plaintiff Susan Christensen, who have used FOSAMAX for the treatment or prevention of osteoporosis, Paget's Disease and/or other off-label uses, have several alternative safer products available to treat their conditions.



37. Merck knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but did not adequately and sufficiently warn consumers, including Plaintiff Susan Christensen, or the medical community, of such risks.

38. As a direct result, Plaintiff Susan Christensen was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Susan Christensen requires and will in the future require ongoing medical care and treatment.

39. Plaintiff Susan Christensen has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

40. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia and Zometa.

41. Aredia is the brand name of pamidronate, which is in a class of prescription drugs called bisphosphonates. Aredia is taken orally and intravenously.

42. Aredia was approved by the United States Food and Drug Administration for treatment of osteoporosis.

43. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

44. Plaintiff Susan Christensen was prescribed and began taking FOSAMAX in 1995.

45. Plaintiff Susan Christensen was prescribed and began taking AREDIA in November 1996 until January 2005.

46. Plaintiff Susan Christensen was prescribed and began taking ZOMETA in June 2003 until November 2005.

47. Plaintiff used FOSAMAX, AREDIA, and/or ZOMETA as prescribed and in a foreseeable manner.

48. As a direct and proximate result of using FOSAMAX, AREDIA, and/or ZOMETA, Plaintiff suffered severe personal injury to her jaw.

49. Plaintiff, as a direct and proximate result of using FOSAMAX, AREDIA, and/or ZOMETA, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

50. Plaintiff used FOSAMAX, AREDIA, and/or ZOMETA, which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

51. Plaintiff would not have used FOSAMAX had Defendant Merck properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms, as they currently exist.

52. Defendant Merck, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

53. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

#### V. COUNTS

##### COUNT I: NEGLIGENCE AGAINST DEFENDANT MERCK

54. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

55. Defendant owed Plaintiff, Susan Christensen, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

56. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

57. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Susan Christensen sustained significant and permanent injury to her jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization,

physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

58. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY AGAINST DEFENDANT MERCK

59. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

60. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Susan Christensen.

61. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

62. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

63. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

64. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

65. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

66. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

67. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

68. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

69. As a direct and proximate consequence of Defendant's conduct, Plaintiff Susan Christensen sustained significant and permanent injury to her jaw. In addition, Plaintiff required and will continue to require healthcare as a result of her injury. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

70. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY AGAINST  
DEFENDANT MERCK

71. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

72. Defendant expressly represented to Plaintiff Susan Christensen, other consumers and the medical community that FOSAMAX was safe and fit for its intended

purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

73. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

74. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

75. Plaintiff Susan Christensen, other consumers, and the medical community relied upon Defendant's express warranties.

76. As a direct and proximate result of Defendant's actions, Plaintiff Susan Christensen sustained serious significant and permanent injury to her jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of her injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.



77. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY AGAINST  
DEFENDANT MERCK

78. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

79. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

80. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

81. Defendant was aware that consumers, including Plaintiff Susan Christensen, would use FOSAMAX for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.

82. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

83. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

84. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

85. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

86. As a direct and proximate result of Defendant's action, Plaintiff Susan Christensen sustained significant and permanent injury to her jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of her injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

87. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION AGAINST  
DEFENDANT MERCK

88. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

89. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's Disease; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

90. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

91. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

92. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

93. Plaintiff Susan Christensen, Plaintiff's doctors, and others relied upon the representations.

94. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

95. As a direct and proximate result, Plaintiff Susan Christensen sustained significant and permanent injury to her jaw. In addition, as a result of her injury, Plaintiff required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

96. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT AGAINST DEFENDANT MERCK

97. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

98. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information, which demonstrated that FOSAMAX was not safer than alternatives available on the market.

99. Defendant had sole access to material facts concerning the dangers and unreasonable risks associated with FOSAMAX.

100. Defendant's concealment of information about the risks associated with taking FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

101. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

102. Plaintiff Susan Christensen, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks associated with taking FOSAMAX that Defendant had concealed from them.

103. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations, Plaintiff Susan Christensen suffered significant and permanent injury to her jaw as well as severe and permanent injuries, including pain, mental and physical anguish and suffering, a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expenses for medical care and treatment due to the injuries caused by FOSAMAX.

COUNT VII: STRICT PRODUCT LIABILITY –  
DESIGN DEFECT AGAINST DEFENDANT NOVARTIS

104. Plaintiff re-alleges the above paragraphs as if fully set forth herein

105. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

106. Aredia as designed, manufactured and sold by Novartis was defective in design or formulation in that it was unreasonably dangerous.

107. Aredia as designed, manufactured and sold by Novartis was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

108. Aredia as designed, manufactured and sold by Novartis was defective due to inadequate warnings because Novartis knew or should have known that the product created a risk of harm to consumers.

109. Aredia as designed, manufactured and sold by Novartis was defective due to inadequate testing.

110. As the proximate cause and result of the defective condition of Aredia as designed, manufactured and sold by Novartis, Plaintiff was injured.

COUNT VIII: STRICT PRODUCT LIABILITY –  
FAILURE TO WARN AGAINST DEFENDANT NOVARTIS

111. Plaintiff re-alleges the above paragraphs as if fully set forth herein

112. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

113. Aredia as designed, manufactured and sold by Novartis was not accompanied by proper warnings regarding possible adverse side effects.

114. Novartis knew or should have known about the possible adverse side effects of Aredia, including osteonecrosis of the jaw.

115. As the proximate cause and result of Novartis' failure to properly warn physicians and consumers, Plaintiff was injured.

COUNT IX: NEGLIGENCE AGAINST DEFENDANT NOVARTIS

116. Plaintiff re-alleges the above paragraphs as if fully set forth herein

117. Novartis designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

118. Novartis had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel, including a duty to assure that users, like Plaintiff, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

119. Novartis failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia in that Novartis knew or should have known that Aredia created an unreasonable risk of osteonecrosis of the jaw.

120. Novartis was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia.

121. As the proximate cause and result of Novartis' negligence, Plaintiff was injured.

COUNT X: BREACH OF EXPRESS WARRANTY AGAINST  
DEFENDANT NOVARTIS

122. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

123. Novartis expressly warranted, by and through statements made by Novartis, that Aredia was safe, effective, and fit for its intended use.



124. Plaintiff, and her agents, relied on the skill, judgment and representations of Novartis.

125. Aredia did not conform to Novartis' express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

126. As the proximate cause and result of Novartis' breach of their express warranties, Plaintiff was injured.

COUNT XI: BREACH OF IMPLIED WARRANTY AGAINST  
DEFENDANT NOVARTIS

127. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

128. Novartis impliedly warranted to Plaintiff, and her agents, that Aredia was of merchantable quality and was safe and fit for its intended use.

129. Plaintiff, and her agents, relied on Novartis' skill and judgment.

130. Aredia was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including severe personal injury to the jaw.

131. As the proximate cause and result of Novartis' breach of its implied warranties, Plaintiff was injured.

132. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

GLOBAL PRAYER FOR RELIEF

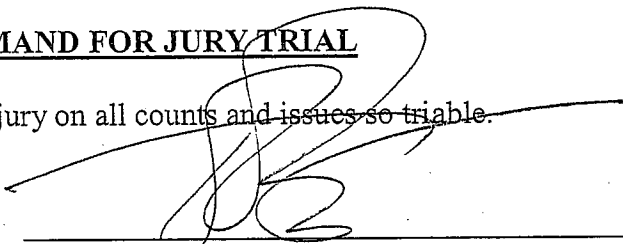
WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;
- c. reasonable attorneys' fees where recoverable;
- d. costs of this action; and
- e. such other additional and further relief as the Court may deem

necessary, appropriate, and just.

**VI. DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and issues so triable.



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